REMARKS

Claims 24-75 are currently pending.

Claim Rejections—35 U.S.C. § 101

I. Applicants note that the Examiner has reiterated his assertion that the claimed invention's asserted utility as a B cell lymphoma marker is a specific utility. *See* Paper No. 20031024, page 2, item 3, second paragraph.

However, the Examiner rejected claims 24-75 under 35 U.S.C. § 101 because "[t]he specification [allegedly] does not assert a substantial utility because the utilities asserted by Applicants requires or constitutes carrying out further research to identify or reasonably confirm a "real world" use." *See* Paper No. 20031024, page 2, last sentence.

Applicants disagree and traverse.

Applicants note that the Utility Guidelines instruct that for substantial utility, "an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a real world context of use..." (see page 2100-32 of M.P.E.P. §2107.1 (I)). The M.P.E.P. further instructs that "... any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility."

The Examiner states that "no protein expression data of SEQ ID NO:56 is provided" (see Paper No. 20031024, page 3, first full paragraph, second sentence). The Examiner also states that in order for a polypeptide to be useful for diagnosis of a disease, "one needs to know, e.g., that the claimed polypeptide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e., overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polypeptide as a diagnostic for a disease." *See* Paper No. 20031024, page 4, line 5-9. The Examiner's present reasons for rejection are the same as in the previous Office Action (see Paper No. 11, page 3, item I).

In response to the previous Office Action, Applicants had submitted Dr. George Komatsoulis's declaration (see response delivered August 27, 2003, Exhibit A), which Applicants resubmit herein (see Exhibit A), to address the above issues.

In the declaration, Dr. Komatsoulis asserts that "the expression of the polynucleotide of SEQ ID NO: 56 was assessed in several hundreds of libraries representing immune and non-immune human tissues, and based on this assessment, expression of the polynucleotide of SEQ ID NO: 56 was only observed in B cell lymphoma cells. More specifically, the expression was preferentially observed in B cell lymphoma, as opposed to normal non-leukemic B cells and hematopoetic cells." *See* Exhibit A, item 4, sentences 1 and 2. Dr. Komatsoulis further stated that SEQ ID NO: 2 included features, such as a transcription factor recognition site, a TATA box, and a polyadenylation signal, that would allow the polynucleotide to be properly translated in to a polypeptide (see Exhibit A, item 5). In summary, Dr. Komatsoulis states that there is differential expression of the polynucleotide of the present invention in B cell lymphoma and no reason to expect that the polynucleotide of SEQ ID NO: 2 would not be translated into a polypeptide.

Applicants remind the Examiner that in order to find the arguments in the Rule 132 Declaration presented herein to be unpersuasive, the Examiner must provide countervailing facts for a proper rebuttal. The proper legal standard, as stated in the M.P.E.P. § 2107.02(III)(A) at pages 2100-39 to 40:

> [I]f the applicant has presented facts that support the reasoning used in asserting a utility, Office personnel must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicant's assertion of utility. In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). The initial evidentiary standard used during evaluation of this question is a preponderance of the evidence (i.e., the totality of facts and reasoning suggest that it is more likely than not that the statement of the applicant is false). (Emphasis added).

Further, the M.P.E.P § 2107.02, at page 2100-42, states

> It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained. If the record as a whole would make it more likely than not that the asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art, the Office cannot maintain the rejection. *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

Applicants find that the Examiner does not present countervailing facts or reasoning sufficient to establish that a person of ordinary skill would not believe the

statements made by Dr. Komatsoulis. Nor does the Examiner respond to each substantive element of Dr. Koumatsoulis's declaration to state reasons why one of skill in the art would not believe the statements.

In the present Office Action, the Examiner only generally acknowledges Dr. Komatsoulis's comments (see Paper No. 20031024, page 7, last paragraph, first sentence) and does not respond to the points made in the statements. The Examiner does state that "Dr. Komatsoulis is not an inventor of the instant invention" (see Paper No. 20031024, page 7, second full paragraph, first sentence). The inventorship of the present invention is immaterial. As a scientist employed by Human Genome Sciences, Inc., Dr. Komatsoulis has access to Applicant's data. The Examiner also quotes from the declaration, emphasizing certain phrases (see Paper No. 20031024, page 7, second full paragraph, second sentence). Applicants are unclear as to the point the Examiner is attempting to make with the emphases. Further, the Examiner claims more evidence is necessary because the declaration was found "insufficient in the absence of objective evidence to support the declarant's assertions" (see Paper 20031024, page 7, last paragraph, second sentence), implying that the Examiner believes Dr. Komatsoulis's reporting of the scientific findings to be biased or faulty or opinion evidence.

Applicants assert that Dr. Komatsoulis's statements are should be considered unbiased and objective evidence because Dr. Komatsoulis is not interpreting the data in any way. He is merely making factual statements concerning data to which he has access, in a truthful and unbiased manner, under penalty or forfeit (see Item 6 of Exhibit A).

To maintain this rejection in proper accordance with the guidelines in the M.P.E.P. given above, the Examiner must either provide factual evidence concerning the claimed invention in order to properly find Dr. Komatsoulis's declaration unpersuasive, or the Examiner must submit a declaration of his own to state that it is impossible that the claimed invention is differentially expressed or translated into polypeptide. The Examiner has done neither in Paper No. 20031024, therefore, the maintenance of this rejection is improper.

Applicants request that the Examiner reconsider and respond to Dr. Komatsoulis's statements regarding (1) the differential expression of the present invention in B cell lymphoma and (2) the characteristics of the polynucleotide sequence of the invention which would allow for its translation into polypeptide in accordance with M.P.E.P. guidelines.

II. The Examiner rejected claims 24-75 under 35 U.S.C. § 101 because the specification allegedly "is not supported by a well-established utility because one of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics [of] the invention." *See* Paper No. 20031024, page 5, first full paragraph. Further the Examiner asserts that because the claims do not allegedly have a substantial utility, it therefore does not have a well-established utility.

Applicants disagree and traverse.

According to the M.P.E.P. § 2107.02B, "[a]n invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible."

Applicants assert that the present invention has a well-established utility. On page 36, lines 6-9 of the specification, it is asserted that the gene is primarily expressed in B cell lymphoma. Applicants submit that one of skill in the art would clearly recognize that such a statement conveys that differential expression exists for the claimed invention, and thus would lead any skilled artisan to immediately appreciate the usefulness of the present invention as a B cell lymphoma marker.

Furthermore, as stated by the Examiner (Paper No. 20031024, page 2, item 3, last sentence), "Applicants' assertion that SEQ ID NO: 56 may be used as a marker for B-cell lymphoma is considered as a specific utility." As discussed above, the asserted utility is substantial (e.g., diagnosing B cell lymphoma is certainly a 'real world use' of public benefit). Finally, this asserted utility is credible based upon preferential expression of the invention in B cell lymphoma tissues as attested to in Dr. Komatsoulis's declaration.

Applicants submit that, for the reasons stated above, the utility asserted in the specification for SEQ ID NO: 56 is indeed *substantial and/or well-established.* Accordingly, Applicants respectfully submit that the rejection of claims 24-75 under 35 U.S.C. § 101 has been obviated. Applicants respectfully request that the rejection of claims 24-75 under 35 U.S.C. § 101 be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. Applicants believe that this application is in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: December 22, 2003 Respectfully submitted,

By _____
Janet M. Martineau
Registration No.: 46,903
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 315-2723

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